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EXAMINER
COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 10/03/2002 12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/821,839	Applicant(s) MA, HONG	
	Examiner Cynthia Collins	Art Unit 1638	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,12-14,17,18,25 and 26* is/are pending in the application.

4a) Of the above claim(s) *25 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,12-14,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3,8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-9, 12-14 and 17-19 in Paper No. 11 is acknowledged. Claims 10, 11, 15, 16 and 19-24 have been cancelled. Claims 25 and 26 are newly added. Applicant argues that because new claims 25 and 26 depend from elected claim 1, they should be considered with the elected Group I invention. This is not persuasive because claims directed to SEQ ID NO:4 (Group VII, claims 22-23) were restricted from claims directed to SEQ ID NOS 1 and 2 in the restriction requirement of May 29, 2002. Accordingly, newly submitted claims 25 and 26 are withdrawn from consideration as being directed to a nonelected invention.

Claims 1-9, 12-14 and 17-19 are pending and are examined on the merits in the instant office action.

Information Disclosure Statement

Initialed and dated copies of Applicant's IDS forms 1449, filed May 15, 2001 and September 28, 2001, Paper Nos. 3 and 8, are attached to the instant Office action.

Claim Objections

Claim 14 is objected to because of the following informality: the genus *Arabidopsis* is not underlined or italicized. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 9 and 12-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to an isolated nucleic acid molecule comprising a gene located on *Arabidopsis thaliana* chromosome 1, the disruption of which is associated with a failure to maintain homolog attachment during meiotic prophase I, said nucleic acid molecule encoding a protein having a cyclin domain and being composed of exons that form an open reading frame having a sequence that encodes a polypeptide approximately 578 amino acids in length. The claims are also drawn to a cDNA molecule comprising said exons, an oligonucleotide, a vector and a transformed plant cell.

The specification describes transposon mutagenesis of *Arabidopsis* and the identification of a mutant, designated *solo dancers* (*sds*), which fails to maintain homolog attachment during meiotic prophase I (Example 1 pages 26-28). The specification also describes the isolation of a wild-type genomic clone from the genomic region corresponding to the transposon insertion in the *solo dancers* mutant, and the isolation of a cDNA (SEQ ID NO:1) corresponding to the genomic clone (Example 2 pages 28-30). The specification discloses that the *SDS* sequence matches a sequenced BAC clone from *Arabidopsis* chromosome 1, and that SEQ ID NO:1

comprises an open reading frame encoding a putative polypeptide of 578 amino acids (SEQ ID NO:2), and that the C-terminus of said polypeptide has amino acid sequence homology to the cyclin box motif of cyclin proteins. Although the specification asserts that the polypeptide of SEQ ID NO:2 is a new type of cyclin, the specification does not assert or demonstrate any specific function for the polypeptide of SEQ ID NO:2. Regarding the claimed invention, the genus as claimed recites no particular nucleotide sequence, and recites no particular function for the isolated nucleic acid or the polypeptide it encodes. The genus as claimed recites that the isolated nucleic acid molecule of the claimed invention comprises a gene located on *Arabidopsis thaliana* chromosome 1, the disruption of which is associated with a failure to maintain homolog attachment during meiotic prophase I, said nucleic acid molecule encoding a protein having a cyclin domain and being composed of exons that form an open reading frame having a sequence that encodes a polypeptide approximately 578 amino acids in length. Applicant is not in possession of all genes or a representative number of genes located on chromosome 1, including variants and allelic mutants that have the recited function. The structure of such genes and their variants and allelic mutants are not predictable based upon the disclosure of SEQ ID NO:1 or SEQ ID NO:4 (see Written Description Guidelines, Federal Register, Vol. 66, No. 4, January 5, 2001, pages 1099-1111).

Claims 1-9, 12-14 and 17-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to an isolated nucleic acid molecule comprising a gene located on *Arabidopsis thaliana* chromosome 1, the disruption of which is associated with a failure to maintain homolog attachment during meiotic prophase I.

As discussed *supra*, the claims recite no particular function for the isolated nucleic acid or the polypeptide it encodes. Furthermore, the specification does not assert or demonstrate any specific function for SEQ ID NOS:1 or 2. Recitation that the disruption of the gene from which a nucleic acid molecule is isolated is associated with a failure to maintain homolog attachment during meiotic prophase I is not a recitation of a particular function for the isolated nucleic acid or the polypeptide it encodes. Absent a known or recited function, it would require undue experimentation for one skilled in the art to make and use the claimed invention, as there are an enormous number of nucleotide sequences corresponding to genes located on *Arabidopsis thaliana* chromosome 1 and there would be no way to eliminate inoperable embodiments on the basis of function. That inoperable embodiments could not be eliminated other than by trial and error is an invitation to experiment.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 12-14 and 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3 and 14 are indefinite in the recitation of "gene". The word gene implies DNA existing in nature that includes coding regions and noncoding regions, such as enhancers,

promoters, and introns. It is suggested that the claim be amended to recite "isolated polynucleotide" or "isolated nucleic acid".

Claim 1 is indefinite in the recitation of "the disruption of which". It is unclear what is disrupted, the gene or the chromosome ?

Claim 1 is indefinite in the recitation of "associated with". It is unclear in what way the disruption is associated with a failure to maintain homolog attachment, because a disruption may be associated with a function in a variety of different ways.

Claim 1 is indefinite in the recitation of "homolog", as it is unclear what type of homlog is intended. It is suggested that the claim be amended to recite "homologous chromosome" rather than "homolog".

Claim 3 is indefinite in the recitation of "approximately". It is unclear how long polypeptide "approximately" 578 amino acids in length would be, because there are different methods of approximation. The metes and bounds of "approximately" are unclear.

Claims 5 and 14 are indefinite in the recitation of "the cyclin domain of SEQ ID NO:2". It is unclear what constitutes the cyclin domain of SEQ ID NO:2, because the location of the amino acids corresponding to the cyclin domain is not recited. It is also unclear whether Applicant intends to claim a nucleic acid molecule encoding a polypeptide comprising only an amino acid sequence at least 70% identical to the cyclin domain of SEQ ID NO:2, or whether Applicant intends to claim a nucleic acid molecule encoding a polypeptide comprising a cyclin domain having an amino acid sequence at least 70% identical to the cyclin domain of SEQ ID NO:2.

Claim 8 is indefinite in the recitation of "comprises an open reading frame having the sequence set forth in SEQ ID NO:1". SEQ ID NO:1 comprises 2144 nucleotides and encodes the polypeptide of SEQ ID NO:2, which comprises 578 amino acids. Accordingly, only 1734 nucleotides of SEQ ID NO:1 encode the amino acids of the open reading frame. Therefore, the open reading frame does not have sequence set forth in SEQ ID NO:1. It is suggested that the claim be amended to recite the location of the open reading in SEQ ID NO:1.

Claim 9 is indefinite in the recitation of "specifically hybridizes". It is unclear under what conditions the oligonucleotide would hybridize to the nucleic acid molecule of claim 1, as different oligonuclotides may specifically hybridize to a nucleic acid molecule under different hybridization conditions. It is suggested that the claims be amended to recite the specific hybridization conditions under which the oligonucleotide would specifically hybridize to the nucleic acid molecule of claim 1.

Claim 14 is indefinite in the recitation of "the open reading frame having a sequence selected from the group consisting of a) SEQ ID NO:1". SEQ ID NO:1 comprises 2144 nucleotides and encodes the polypeptide of SEQ ID NO:2, which comprises 578 amino acids. Accordingly, only 1734 nucleotides of SEQ ID NO:1 encode the amino acids of the open reading frame. Therefore, the open reading frame does not have sequence set forth in SEQ ID NO:1. It is suggested that the claim be amended to recite the location of the open reading in SEQ ID NO:1, or to simply recite that the isolated nucleic acid comprises a sequence of SEQ ID NO:1.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9, 12-14 and 17-19 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims are drawn to an isolated nucleic acid molecule comprising a gene located on *Arabidopsis thaliana* chromosome 1, the disruption of which is associated with a failure to maintain homolog attachment during meiotic prophase I, said nucleic acid molecule encoding a protein having a cyclin domain and being composed of exons that form an open reading frame having a sequence that encodes a polypeptide approximately 578 amino acids in length. The claims are also drawn to a cDNA molecule comprising said exons, a nucleic acid molecule encoding an amino acid sequence at least 70% identical to the cyclin domain of SEQ ID NO:2, a nucleic acid molecule encoding an amino acid sequence at least 50% identical to SEQ ID NO:2 over the entire length of SEQ ID NO:2, a nucleic acid molecule encoding SEQ ID NO:2, a nucleic acid molecule that comprises an open reading frame having the sequence set forth in SEQ ID NO:1, an oligonucleotide, and an isolated nucleic comprising an open reading frame having a sequence selected from the group consisting of: SEQ ID NO:1, a sequence at least 80% identical to SEQ ID NO:1, a sequence encoding SEQ ID NO:2, a sequence encoding a polypeptide having at least 50% or at least 70% identity to SEQ ID NO:2, a sequence encoding a polypeptide having at least 70% identity to the cyclin domain of SEQ ID NO:2, and a nucleotide sequence that hybridizes under stringent conditions to SEQ ID NO:1. Additionally the claims are drawn to a vector, a transformed plant cell.

First, the claims do not recite a specific function for the nucleic acid of SEQ ID NO:1 or for the polypeptide of SEQ ID NO:2, or for the sequences having percent identity to SEQ ID NOS: 1 or 2 or for the sequences hybridizing to SEQ ID NO:1. The recitation that the disruption of a gene located on *Arabidopsis thaliana* chromosome 1 is associated with a failure to maintain homolog attachment during meiotic prophase 1 is not a specific function, because the disruption of genes other than the gene corresponding to SEQ ID NO:1 may be associated with a failure to maintain homolog attachment during meiotic prophase 1, and because failure to maintain homolog attachment during meiotic prophase 1 does not explain what the polypeptide of SEQ ID NO:2 does. In the absence of a specific functional limitation, one could not identify useful sequences having percent identity to SEQ ID NOS: 1 or 2 or useful sequences hybridizing to SEQ ID NO:1, since some of the differences between the homologous or hybridizing sequences and SEQ ID NOS 1 and 2 would inactivate the function of the polypeptide. Because the claimed invention is not supported by a specific asserted utility for the reasons set forth above, credibility cannot be assessed.

Second, the claimed invention lacks utility because no function has been demonstrated for the nucleic acid of SEQ ID NO:1 or the polypeptide of SEQ ID NO:2. Although the specification discloses that the C-terminus of SEQ ID NO:2 has amino acid sequence homology to the cyclin box motif of cyclin proteins and asserts that the polypeptide of SEQ ID NO:2 is a new type of cyclin (page 29), no empirical data is provided to support a cyclin function. While empirical data is not required for patentability, the state of the art recognizes that a functional assignment based on amino acid homology may be useful to categorize a sequence as potentially

encoding a particular protein or provide a starting point for verifying the function of the protein it encodes, it does not replace empirical data for confirming its function.

Third, Applicant's claimed nucleic acid sequence lacks substantial utility under current utility guidelines. Although the specification suggests that the gene of the instant invention has utility in the manipulation and regulation of fertility (page 2), the specification does not disclose how to use the claimed nucleic acid molecules to manipulate or regulate any aspect of fertility in a plant. Applicant does not teach how the claimed nucleic acid sequences would be substantially beneficial to the public. It is apparent that further research, not considered to be routine experimentation, would be required before one of skill in the art would know how to use the claimed invention. It has been established by the courts that a utility which requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use is not a substantial utility.

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." (*Brenner v. Manson*, 383 U.S. 519 (1966)).

Thus, while a nucleic acid sequence that can be used to manipulate or regulate plant fertility has substantial benefit to the public, Applicant does not disclose such a nucleic acid, and one skilled in the art cannot conclude that a nucleic acid of SEQ ID NO:1 or a nucleic acid encoding SEQ ID NO:2 would affect plant fertility in a useful way based upon Applicant's disclosure.

Applicant's invention is not refined to the point where specific benefit exists in currently available form. As set forth above, one skilled in the art cannot readily take Applicant's claimed

invention and derive immediate benefits from it based upon Applicant's disclosure. Accordingly, the claimed invention lacks a real world use. (see Utility Examination Guidelines published in the Federal Register, Vol. 66, No. 4, Friday, January 5, 2001, Notices, pages 1092-1099).

Claims 1-9, 12-14 and 17-19 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Feng et al. (GenBank Accession B10183, 14 May 1997).

Claim 9 is drawn to an oligonucleotide between about 15 and 100 nucleotides in length that specifically hybridizes to the nucleic acid of claim 1.

Feng et al. teach a nucleic acid sequence which comprises oligonucleotides between about 15 and 100 nucleotides in length that would specifically hybridize to the nucleic acid of claim 1.

Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Bohmert et al. (EMBO J. 1998 Jan 2;17(1):170-80).

Claim 14 is drawn to an isolated nucleic acid molecule comprising an open reading frame of a gene located on *Arabidopsis* chromosome 1, the open reading frame having a sequence that hybridizes with SEQ ID NO:1 under stringent conditions.

Bohmert et al. an isolated nucleic acid molecule comprising an open reading frame of the AGO1 gene located on *Arabidopsis* chromosome 1, the open reading frame having a sequence that hybridizes with SEQ ID NO:1 under stringent conditions. While Bohmert et al. do not explicitly teach the specific hybridization conditions recited in the claim, the sequence taught by Bohmert et al. would necessarily hybridize to SEQ ID NO:1 under the recited conditions, as section f) of claim 1 does not limit the size of the sequence that would hybridize to SEQ ID NO:1.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Phuong Bui

PHUONG T. BUI
PRIMARY EXAMINER

9/30/02

CC
September 28, 2002